



SCIENTIFIC INVESTIGATION

PROCEDURE ID: YMP-LBNL-QIP-SIII.0

REV. 1, MOD. 1

EFFECTIVE: 1/17/97

1. PURPOSE

This quality implementing procedure (QIP) describes considerations for planning scientific investigations and the format and use of scientific and field notebooks for recording research and engineering activities. Notebook entries (1) document research in sufficient detail so that other researchers, without recourse to the original researcher, can repeat the experiment with equivalent results and (2) document all information that support findings distributed in publications, conference papers, reports, and other means of communication to the scientific community.

2. SCOPE

Proper planning and control of scientific and engineering investigations are crucial to the accuracy, reliability, and reproducibility of the desired results. The scientific notebook system is an important means of recording and controlling work that requires professional judgment or trial and error methods. The "field" notebook is actually a "scientific" notebook that is frequently used in the field. As such, scientific and field notebooks are implemented in the same way. Scientific and field notebooks can be either bound notebooks or ringed binders.

This procedure covers the planning of work to ensure work is accomplished under suitably controlled conditions. The procedure also addresses, notebook initiation and identification, first-entry content, on-going entries, summary and conclusion entries, periodic notebook duplication and dual storage, and notebook review and close-out. Scientific and field notebooks implement Yucca Mountain Project-Lawrence Berkeley National Laboratory (YMP-LBNL) quality assurance (QA) documentation requirements. Only notebook contents that comply with these QA requirements can be used in the design and licensing of the proposed Yucca Mountain nuclear waste repository.

3. PROCEDURE

3.0 Scientific Investigation Planning and Control.

All quality affecting work shall be conducted in accordance with approved YMP-LBNL QIPs. Scientific investigations shall be controlled in accordance with this procedure.

- 3.0.1 The principal investigator or appropriate manager shall plan scientific and engineering investigations to include the following elements as appropriate;
- A. Definition of the work scope, objectives, and primary tasks;
 - B. Identification of scientific approach or technical methods used to collect, analyze, or study results;
 - C. Identification of applicable standards and criteria;
 - D. Identification and application or development of appropriate implementing documents per YMP-LBNL-QIP-5.2 *Preparing Quality and Technical Implementing Procedures*;
 - E. Identification of field and laboratory testing equipment;
 - F. Identification of required records and the recording of objective evidence of the results;
 - G. Identification of quality assurance program verifications to overview the work performed;
 - H. Identification of prerequisites, special controls, environmental conditions, processes or skills;
 - I. Identification of computer software.
 - J. Identification and traceability information for unqualified data, when used.
 - K. Qualification of previously-unqualified data directly relied upon to address safety and waste isolation issues.
 - L. Validation of models of natural phenomena.
- 3.0.2 The principal investigator or appropriate manager shall coordinate efforts with organizations providing input to or using the results of the investigation. The principal investigator and affected organizations shall collectively determine the accuracy, precision, and representativeness of the results.
- 3.0.3 The principal investigator or appropriate manager shall ensure that planning documents are reviewed per YMP-LBNL-QIP-6.1, *Document Review*.
- 3.0.4 The principal investigator and his/her staff shall perform and control investigations by use of scientific notebooks, field notebooks, and/or technical implementing procedures.

- 3.0.5 The principal investigator and staff shall document, in the appropriate scientific or field notebook, the use of, and results derived from technical implementing procedures.

3.1 Notebook Initiation and Identification.

The scientific staff shall:

- 3.1.1 use bound notebooks or ringed binders to document the work;
- 3.1.2 make entries using ink or other indelible marker. Dark colors shall be used to facilitate photocopying (to meet record-duplication requirements);
- 3.1.3 number every page; and,
- 3.1.4 enter the following identifying information on the first page of each scientific or field notebook:

A. Project information:

- 1. Work Breakdown Structure (WBS)) element and/or Site Characterization Plan (SCP) number,
- 2. WBS title and/or SCP title, and
- 3. account number(s)

B. unique identifying alphanumeric; for example:

YMP-LBNL- [Initials] -1;

C. notebook starting date;

D. printed name, signature, and handwritten initials of all staff members making entries or recording information;

E. designated owner of the notebook; and

F. project status.

3.2 First Entry.

The Notebook's first entry shall include, for the Project or Task:

- 3.2.1 the objective;
- 3.2.2 a description of the work expected to be performed, or a clear reference to a planning or implementing document containing that information;
- 3.2.3 equipment (giving consideration to the type, accuracy, and range of the equipment needed), materials, or procedures that may be used throughout the notebook; and
- 3.2.4 status of investigation as baseline for future entries.

3.3 On-Going Entries.

Ongoing entries shall include the following, as applicable:

- 3.3.1 A description of the work as it was performed, with actions sufficiently documented so that the results are repeatable and confirmable by a person of equivalent competence. Such actions include the use and validation of models of natural phenomena and the justification for the intended use. Validation is achieved through comparison of results with laboratory or field experiments or through technical review.

Note: When a repetitive investigative process is required but is not sufficiently complex to warrant development of a formal technical procedure, a notebook procedure may be written and used by the principal investigator(s), as follows:

- A. The principal investigator (or designee) shall write the notebook procedure clearly in the scientific or field notebook, including detailed purpose and scope statements, the methodology or steps to be followed, and a name or title to be cited in the notebook whenever the thus-described investigative process is used.

- B. The principal investigator shall obtain an independent technical review to confirm that the notebook procedure is an appropriate methodology to achieve the desired results.
 - C. The independent technical reviewer shall sign and date the notebook at the end of the notebook procedure to show concurrence.
- 3.3.2 Unique identification of the technical procedures, software, equipment, materials, standards, and chemicals used;
- 3.3.3 sample and data identification, traceability and data qualification information (see also Section 3.7), description of data reduction to permit independent reproducibility by a qualified individual, modeling information (see Section 3.8), and requirements for sample preservation or handling, or any other criteria;
- 3.3.4 Detailed documentation of deviations from standardized procedures;
- 3.3.5 Corrections to errors made by:
 - A. drawing a single line through the erroneous information (which does not obliterate that information),
 - B. correcting the information nearby with an explanation for the correction (if warranted), and
 - C. adding the initials of the person making the correction and the date of the correction;
- 3.3.6 Securely attach (by gluing, taping, etc.) associated charts and figures where relevant;
- 3.3.7 The date and signature or handwritten initials of each person making the entry or performing the work; and
- 3.3.8 The notation “intentionally left blank” on all blank pages.

3.4 Summary and Conclusion Entries.

The principal investigator or appropriate manager shall ensure that the results of sub-tasks, tasks, and projects are summarized in each notebook. Each summary shall include the following elements:

- 3.4.1 a brief description of observations or results and their acceptability or non-acceptability, and
- 3.4.2 interim conclusions drawn from the results or observations.

3.5 Periodic Notebook Duplication.

The principal investigator or appropriate manager shall ensure that laboratory and field notebooks that remain in use for more than 1 year shall be (1) photocopied and (2) the copy submitted to the YMP-LBNL Records Processing Center for safe, duplicate storage.

3.6 Notebook Review and Close-out.

- 3.6.1 After the conclusions of a scientific investigation have been finalized, but before those conclusions have been formally published, the principal investigator or appropriate manager shall ensure that a documented technical review of the results of the scientific investigation is performed by an independent technical reviewer. The reviewer shall be selected by the principal investigator or appropriate manager, and qualified per requirements of YMP-LBNL-QIP-2.1 in the appropriate field(s) of research.
 - A. The review shall be limited in scope and depth to an examination of the general technical validity of the data and analysis as documented in the scientific notebook, and an estimation of whether the calculations are sufficiently described to allow replication by an independent peer.
 - B. The independent technical reviewer shall use the following categories of review criteria:
 - For data that have not previously been reviewed, the reviewer shall review the scientific notebook and/or other source documents only.

- For data that have previously been reviewed but have subsequently received additional analysis or refinement, the reviewer shall check the additional analysis.
 - C. The independent technical reviewer shall document the completed review, including the pages reviewed and other pertinent information, using the “YMP-LBNL *Document Review/Comment Resolution Form*” from the YMP-LBNL-QIP-6.1, *Document Review*. All applicable sections of the form shall be completed.
- 3.6.2 After completion of the independent technical review, the scientific notebook shall be reviewed by an independent quality assurance reviewer, who shall:
- A. confirm that the documentation requirements of Sections 3.1-3.4 of this procedure and YMP-LBNL-QIP-17.0, *Submitting Records to the YMP-LBNL Records Processing Center*, have been met, (i.e., that the Project Office will accept the scientific and field notebook data for input to the characterization of the Yucca Mountain nuclear waste repository), and
 - B. provide documentation of the review, including the pages reviewed and other pertinent information, using the “YMP-LBNL *Document Review/Comment Resolution Form*” from YMP-LBNL-QIP-6.1, *Document Review*.
- 3.6.3 After completion of the independent technical and QA reviews, the scientific notebook shall be duplicated (photocopied) for submission to the YMP-LBNL Records Processing Center ensuring that:
- A. the duplicates are legible, and
 - B. the requirements of the YMP-LBNL-QIP-17.0 are followed.

3.7 Qualification and Use of Data.

- 3.7.1 Unqualified data may be used in YMP-LBNL scientific investigations when traceability to its status as unqualified is maintained, it is data considered to be established fact by the scientific and engineering community, or it is not directly relied upon to address safety and waste isolation issues.

- 3.7.2 Data that is directly relied upon to address safety and waste isolation issues shall be qualified, by one or a combination of the following:
- A. a documented determination that the data was generated under controls similar to, or more stringent than, those of DOE/RW/0333P, *Quality Assurance Requirements and Description* (QARD).
 - B. use of another set of data to corroborate the unqualified data, including a clearly documented justification for selecting the corroborating data set.
 - C. confirmatory testing.
 - D. peer review per QARD requirements.
- 3.7.3 Data qualification shall be documented, and this documentation shall include the factors used to determine which qualification method(s) are used, the acceptance criteria for data thus qualified, and (when qualification methods 3.7.2 A, B or C are used) a documented review to determine application suitability for the qualified data.

3.8 Development and Use of Models.

- 3.8.1 When models of natural phenomena are developed, the development process and principal lines of investigation considered shall be documented. The selection and use of such models shall be documented and justified.
- 3.8.2 Each model shall be validated to confirm that the mathematical representation appropriately depicts the natural phenomena. This shall be accomplished by comparing analysis results against laboratory, field experiment, natural analogue study, analytical or semi-analytical solutions, and/or observational data not used in the original development of the model. When such data or solutions are not available, alternative validation approaches shall be used and documented. Use of peer review as an alternative validation method shall conform with QARD requirements for peer review consideration criteria.

4. RECORDS MANAGEMENT

4.1 Lifetime

Scientific and Field Notebooks
Any other support information

4.2 Non-permanent

None

4.3 Controlled Documents

None

4.4 Records Center Documents

Records associated with this procedure shall be submitted to the YMP-LBNL Local Records Processing Center, in accordance with YMP-LBNL-QIP-17.0.

5. RESPONSIBILITIES

5.0 The **principal investigator** or **appropriate manager** is responsible for planning scientific or engineering investigations.

5.1 All **staff** that make entries into a laboratory or field notebook shall implement the requirements of this procedure.

5.2 All **staff** shall inform the Quality Assurance Manager upon close out of a scientific or field notebook.

5.3 Each **owner** of a laboratory or field notebook shall duplicate notebooks that are still in use for more than one year and give the photocopies to the YMP-LBNL Records Processing Center for duplicate storage.

5.4 The **principal investigator** or **appropriate manager** shall submit notebooks to YMP-LBNL Records Processing Center upon their completion or the end of task or project.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

None.

6.2 Definitions

Project. Activity or Sub-activity associated with Site-Characterization-Plan-Breakdown (SCPB) and Work-Breakdown-Structure (WBS).

Staff. Any person performing work in support of the site-characterization or engineered-construction of the proposed Yucca Mountain geologic repository.

7. REFERENCES

DOE/RW/0333P, *Quality Assurance Requirements and Description*

YMP-LBNL-QIP-2.1, *Qualifying Personnel*

YMP-LBNL-QIP-5.2, *Preparing Quality and Technical Implementing Procedures*

YMP-LBNL-QIP-6.1, *Document Review*

YMP-LBNL-QIP-17.0, *Submitting Records to the YMP-LBNL Records Processing Center*

8. ATTACHMENTS

None.

9. REVISION HISTORY

9/22/95 - Revision 0, Modification 1:

Revised procedure to: direct staff to comply with approved implementing procedures for quality affecting work; authorize and provide instructions for developing notebook procedures; and properly classify records as lifetime or non-permanent.

10/22/96 - Revision 1, Modification 0:

Revised procedure to reflect requirements changes in QARD, Rev. 5.
Added information on performance of independent technical reviews of data.
Made general administrative and readability improvements.

1/10/97 - Revision 1, Modification 1:

Changed context in Sect. 3.2.3 to include consideration for type of equipment.

10. APPROVALS

Preparer:

Date

Technical Reviewer:

Date

Technical Reviewer:

Date

QA Reviewer:

Date

Quality Assurance Manager Approval:

Date

Project Manager Approval:

Date